

Appl. No. 10/761,596  
Amendment Dated March 8, 2006  
Reply to Office Action of September 9, 2005

Confirmation No. 4255

### **REMARKS**

Applicant respectfully requests entry of the Amendment and reconsideration of the claims. Applicant respectfully traverses the pending rejection under 35 U.S.C. § 103(a). Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

#### **Interview Summaries**

Applicant thanks the Examiner and the Examiner's supervisor for their telephone interviews with Applicant's agent David Heller (Reg. No. 43,384) on January 12, 2006, and February 7, 2006. David Heller's interview summaries are attached.

#### **Petition for Extension of Time**

It is noted that a three-month petition for extension of time is necessary to provide for the timeliness of the response. A request for such an extension is made extending the time for response from December 9, 2005 to March 9, 2006.

#### **Rejection Under 35 U.S.C. § 103(a)**

Claims 11-13, 17 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Adams et al., 6,165,975 and Papandreou et al., 6,171,232 and Salzman et al., 5,958,427 and Klokke-Bethke et al., 5,370,862 and Veronesi et al., 5,580,576. The Examiner has stated that Klokke-Bethke et al. disclose pharmaceutical aerosol sprays containing effective amounts of nitric oxide agonist, nitroglycerin; that Veronesi et al. disclose pharmaceutically/storage stable, water resistant formulations comprising nicorandil (a nitric oxide agonist) and pharmaceutically acceptable excipients; that Adams et al. teach pharmaceutical compositions comprising effective amounts of either sodium nitroprusside, 3-morpholinopyrrolidine, molsidomine or Sirtoso-N-acetyl penicillamine (SNAP) and a pharmaceutically acceptable carrier; that Papandreou et al. teach that sodium prusside is a generally approved nitric oxide donor pharmaceutical; and that Salzman et al. teach pharmaceutical compositions containing effective amounts of nitric oxide donor compounds.

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The Examiner acknowledges that these prior art references do not specifically disclose formulating the compositions into a kit with instructional material that is specified for oral administration of the nitric oxide donor and/or nitric oxide agonist compositions. Although not specifically acknowledged in the Office Action, Applicant also notes that none of the prior art references discuss administering the composition to ameliorate symptoms of insulin resistance, or instructions that specify administering the composition for same.

The Examiner states that the test for determining patentability of kit claims relates to the functionality of the printed matter, citing *In re Ngai*, 367 F.3d 1336 (Fed. Cir. 2004) and *In re Gulack*, 703 F.2d 1381 (Fed. Cir. 1983). The Examiner states that in the instant case the instructional material is not functionally related to the compositions containing nitric oxide donor and/or nitric oxide agonists because these compositions can function as active effective drugs even in the absence of instructions material. The Examiner states that therefore, following the rationale in *Ngai* and *Gulack*, one can conclude that the instructional material does not patentably distinguish the claimed composition over the prior art. The Examiner also states that the instruction material for using the nitric oxide donor and/or the nitric oxide agonist compounds used to ameliorate symptoms of insulin resistance relates to intended use and does not further limit or define the overall pharmaceutical compositions. Thus, the sole basis for the rejection is the Examiner's contention that the instruction materials should not be considered relevant to distinguishing the instantly claimed kit from the prior art.

Applicant respectfully traverses this rejection.

Applicant submits that the instant case is distinguished from *In re Ngai* and *In re Gulack*, and that the instructional materials are functionally related to the composition in the instant kit claims.

In *Ngai*, it was not contested that the prior art taught (a) each of the physical elements to *Ngai's* kit, for use in amplifying RNA, as well as (b) instructions for using those elements for amplifying RNA, i.e., for achieving the same function that *Ngai* taught. *Ngai* taught an improved methodology.

In contrast, in the instant application there is no prior art teaching (a) any of the physical elements of the instantly claimed kit for use in treating insulin resistance, nor any prior art teaching (b) instructions for using those physical elements for treating insulin resistance, i.e.,

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instructions for achieving the same function as the instant applicant teaches, with the physical elements that the instant applicant teaches.

In *Ngai*, the court distinguishes *Ngai*'s invention from that of *Gulack*'s by stating that "in *Gulack*, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter."

In contrast, applicant submits that in the instantly claimed invention, drugs sold in modern society depend on, and are functionally tied to, the printed matter sold with that drug. The instant case does not fall within the facts of *Gulack* and is distinguished from *Ngai*.

In *Ngai*, the prior art taught the physical components of the kit to produce the desired result. In contrast, in the instant case the prior art does not teach or motivate one to use the physical components of the kit to produce the desired result.

*Ngai* clarifies but does not overturn the law of *In re Gulack*, "[The] [d]ifference between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter." Thus, in order to qualify under *Gulack*, the printed matter must be functionally related to the underlying object. "The critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate."

Applicant respectfully submits that in the instantly claimed kit, the instructions are functionally related to the compositions. One does not, and indeed cannot sell drugs without instructions for use. Such sale violates American laws. In any event, if one did sell drugs without the instructions for their use, the functionality of the drug would be lost: e.g., a pharmacy filled with unlabelled drugs would not be functional. Applicant submits there is no case law or statutory law, including *In re Ngai*, stating that each element in a kit claim must physically interact with the other elements, i.e., that the instructions must physically interact with the other elements. *Ngai* only states that there must be functionality to the printed matter; Applicant respectfully submits that the applicant has established that such functionality exists in the instant case. Furthermore, this functionality exists at the point of invention.

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Given that the instructions in the instantly claimed kit are functionally related to the rest of the kit's elements, the content of these instructions must be considered relevant to distinguishing the instantly claimed kit from the prior art. Since none of the cited prior art discloses or teaches instructions for oral administration to ameliorate symptoms of insulin resistance, Applicant respectfully submits that the instantly claimed kit is novel and inventive over the prior art.

As set out in the attached interview summary, the Examiner and her Supervisor took the position that the kit claims were not patentable on the basis that the instructions do not modify the composition, and that the instructions are not an active agent. The Examiner and her Supervisor took the position that, in order to be patentable, the elements of the kit claim must physically interact with each other.

Regarding the requirement by the Examiner that elements of a kit must interact, Applicant submits the following case. In *Ex parte Adams and Ferrari*, 177 U.S.P.Q. 21, Patent Office Board of Appeals, 1974, (a copy of which is enclosed for your convenience), the Board of Appeals considered a rejection from an Examiner in a claim directed to the combination of a fireplace having a metallic surface on its fire chamber, a damper in its flue, and a magnet attachable to the metallic surface for indicating the closed condition of the damper. The Examiner rejected the claim on the basis that there was no co-operation present between the fireplace and the magnetic pendant except for what the user may mentally choose to indicate. The Board reversed the decision of the Examiner, and held specifically that "[w]e know of no requirement in the statute of direct mechanical interaction between the elements of a combination. As long as the over-all result has utility and is unobvious, the elements of a patentable combination may function independently". In the instant case, there is no direct mechanical interaction between the elements of the combination in the kit, however, the elements of the instant kit do function in co-ordination. i.e., the medicine is not functional without the directions, and the directions are useless without the medicine.

The Examiner has also made comments regarding the limitation "structurally modified to preferentially release nitric oxide in the liver", and with respect to claim 17. Applicant submits that, in light of the arguments presented above, these comments are now moot.

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In view of the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C.  
§ 103(a).

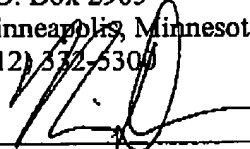
**CONCLUSION**

In view of the above remarks, Applicants respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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Date: March 8, 2006

  
Brian D. Dorn  
Reg. No. 57,395

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Ex parte Adams and Ferrari

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## Patent Office Board of Appeals

Ex parte ADAMS AND FERRARI

Patent issued Jan. 9, 1973

Opinion dated June 21, 1972.

## PATENTS

## 1. Patentability — Aggregation or combination — In general (§51.151)

Statute does not require direct mechanical interaction between elements of combination; as long as overall result has utility and is unobvious, elements of patentable combination may function independently.

## Particular patents—Indicator

3,708,897, Adams and Ferrari, Closed-Damper Indicator for Fireplace, claims 6 to 8 of application allowed.

## Appeal from Group 336.

Application for patent of William J. Adams and Eugene A. Ferrari, Serial No. 815 987, filed Apr. 14, 1969. From decision rejecting claims 6 to 8, applicants appeal (Appeal No. 090-08). Reversed.

JOSEPH F. COLE, Burlingame, Calif., for applicants.

Before PARKER and MATTEAN, Examiners in Chief, and ARNOLD, Acting Examiner in Chief.

ARNOLD, Acting Examiner in Chief.

This is an appeal from the final rejection of claims 6, 7 and 8, which are the only claims pending in the application.

The references upon which the examiner has relied are:

Igelstroem	911,991	Feb. 9, 1909
Moore	2,119,825	June 7, 1938
Harris	2,977,082	Mar. 28, 1961

All claims stand rejected under 35 U.S.C. 103 as unpatentable over Igelstroem or Moore in view of Harris. The examiner's position, as stated in the final rejection of November 23, 1970, which has been incorporated into the Examiner's Answer by reference, is that:

"The references show suggestive forms of pendants and since magnets are well known it would be obvious to use similar means to suspend the pendants of the references even in the absence of such art as Harris. The references show some form of support to which the pendant, etc. is attached and to merely associate the device with a fireplace or any other support would be obvious to those skilled in art. Any 'cooperation' such as serving to indicate the position of the fireplace damper is merely a mental coopera-

tion and cannot be considered to structurally distinguish over the references."

We have reviewed the rejection of the claims and the references as applied thereto in light of the arguments presented by Appellants and examiner in support of their respective positions, but find no proper basis for supporting the position of the examiner.

The statement on page 1 of the Examiner's Answer that "the references, particularly the patent to Igelstroem, do show the combination of a support to which is removably secured a pendant assembly" is, of course, correct, as to what the references disclose, but it is not an explanation of how the references anticipate or make obvious the combination claimed.

Parent claim 6 is directed to the combination of a fireplace having a metallic surface in the fire chamber; a damper in its flue; means attachable to the metallic surface for indicating a closed condition of the damper; the indicating means comprising a permanent magnet attached to one end of a connector for attachment to the metallic surface and a telltale at the other end of the connector; and a metallic strip fixed to the exterior of the fireplace. We find nothing in the references, whether considered singly or in combination, which discloses or suggests such combination of elements for the purpose disclosed.

[1] The examiner states that "no cooperation is present between the fireplace and the pendant except for what the user may mentally choose it to indicate" (page 3, lines 2-4 of the Examiner's Answer). We do find this argument inadequate and inaccurate. The relation of the telltale to the fireplace structure is admittedly a passive one, but it is nevertheless one of cooperation. We know of no requirement in the statute of direct mechanical interaction between the elements of a combination. As long as the over-all result has utility and is unobvious, the elements of a patentable combination may function independently. In the instant device, the magnetic pendant hanger cooperates with the metallic strip in the fireplace and the metallic strip exterior of the fireplace to indicate a condition of the fireplace flue. Such relation of parts is certainly not made obvious by the references before us. We are accordingly obliged not to support the rejection of the claims.

The decision of the examiner is reversed.